UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SAMANTHA PELUSO, on behalf of herself and all others similarly situated, Plaintiff, v. SHIRE U.S., INC., a New Jersey Corporation; SHIRE, LLC, a Kentucky Limited Liability Company and JOHN DOES 1-100; ABC CORPS 1-100, inclusive, Defendants.	)	**Class Action** **Jury Trial Demanded**

CLASS ACTION COMPLAINT

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Plaintiff, Samantha Peluso, individually and on behalf of all others similarly situated (the "Class"), brings this action against Defendants Shire LLC and Shire U.S., Inc. (collectively, "Shire" or "Defendants"), and alleges, based on personal knowledge, investigation, and information and belief as to all other matters, as follows:

I. NATURE OF ACTION

1. This is a putative class action comprised of consumer indirect purchasers of Adderall XR, a popular prescription medication prescribed to treat attention deficit hyperactivity disorder ("ADHD").

2. Defendants manufacture and sell Adderall XR. Defendants sell Adderall XR and also sell and/or have sold it to generic companies to sell as an "Authorized Generic" product.

3. Branded pharmaceutical drugs are submitted to the U.S. Food and Drug Administration ("FDA") through a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355, *et seq*. The FDA approves the NDA upon a showing – through several randomized controlled clinical trials – that the drug is safe and effective for the proposed indication.

4. Generic drugs are prescription drugs that contain the same active ingredient as their branded counterparts. In contrast to the extensive clinical trial requirements for branded drugs, generic drug approval is subject to the Hatch-Waxman Act of 1984, 21 U.S.C. § 355(j), *et seq*., which was enacted by Congress to streamline generic drug approval and encourage generic drug competition.

5. Generic drug applications are referred to as Abbreviated New Drug Applications ("ANDA"), and are approved by the FDA upon a showing that the ANDA product is bioequivalent (i.e., no substantial differences) and pharmaceutically equivalent to the FDA-approved reference listed drug ("RLD"), which usually refers to an NDA drug. Upon granting final approval for a generic drug, the FDA will typically state the generic drug is "therapeutically

equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD branded drug.

6. Patients and their prescribing physicians can thus expect to substitute "A/B rated" generic drugs with the full expectation that the generic drug will carry the same safety and efficacy profile as the branded RLD. Generic drug approval is streamlined because generic drugs are typically sold at much lower prices than their branded equivalents.

7. The branded pharmaceutical company may also elect to license what is commonly referred to as an "Authorized Generic" version of its branded drug. "Authorized Generic" drugs are launched by brand manufacturers as a means to retain revenue upon generic entry, and typically involve the brand manufacturer licensing its NDA formulation (as well as any intellectual property) to an authorized generic partner. The licensee partner then sells the authorized generic as a generic version of the brand drug, and remits a royalty to the brand manufacturer. For major drugs, the licensing of an authorized generic has become commonplace.

8. Upon the market entry of a generic drug, substitution of the brand drug for the generic ("generic substitution" or "generic erosion") occurs very swiftly. Typically, the brand drug (which holds 100% market share as of generic entry) will lose as much as 70% within weeks of generic entry. By one year, the process of generic erosion usually results in the brand drug holding 10% or less market share, with generic equivalents capturing the remaining 90%.

9. There are several forces that drive generic substitution, all of them rooted in the premise that generic drugs are less expensive than their brand-name counterparts. First, most states have generic substitution laws that mandate and require pharmacies to substitute therapeutically equivalent generics absent exceptional circumstances. These statutes are enacted as consumer protection laws, and are designed to ensure that consumers benefit from the availability of less costly medications.

10. Second, managed care organizations ("MCOs") including health insurance companies and pharmacy benefits managers ("PBMs") – as entities that reimburse a large portion of prescription drug costs – encourage such substitution by their insured patients and physicians through the use of prescription drug formularies. Prescription drug formularies have been implemented by MCOs as a cost-sharing mechanism to control ever-increasing prescription drug costs and to encourage insured patients to utilize cheaper drugs. As co-payors for prescription drugs, it is in both the insurer's and the insured's interest that less expensive generic equivalents be utilized when available.

11. Defendants engaged in a number of illegal schemes meant to delay the entry of generic competition and subsequently maintain the market share of the more expensive branded Adderall XR post-generic entry. Namely, Defendants filed and prosecuted non-meritorious patent litigation, entered into anticompetitive reverse payment agreements to delay generic entry, and once generics entered the market, contracted with MCOs and PBMs via collusive rebate agreements that forced millions of patients to purchase Adderall XR or generic AXR for a higher copay or coinsurance than they otherwise would have paid for generic AXR absent such rebate agreements.

12. Defendants' conduct constitutes an illegal restraint of trade and/or attempt at monopolization in violation of both federal and state antitrust statutes as well as state consumer protection acts, which harmed consumers by delaying generic entry, and after generic entry, by illegal rebate contracting with MCOs, both strategies operating to force many consumers to purchase the more expensive brand-name medication sold by Defendants.

13. Plaintiff therefore brings this action on behalf of themselves and a New Jersey Class of indirect purchasers of Adderall XR and generic AXR, asserting that Defendants' anti-competitive behavior (in violation of the Sherman Act, the New Jersey Antitrust Act, and New

Jersey's consumer protection laws) violates New Jersey's Anti-Trust Act, *N.J.S.A.* 56:9-1, *et seq.* and New Jersey's Consumer Fraud Act *N.J.S.A* 56:8-1, *et seq.*

II. PARTIES

14. Plaintiff Samantha Peluso, is, and at all times relevant hereto was, a citizen and resident of Passaic County, New Jersey. During the Class Period, Ms. Peluso was prescribed Adderall XR in Passaic County for purposes other than resale.

15. Defendant Shire U.S., Inc. is a New Jersey corporation with a registered agent located in West Trenton, New Jersey 08628 and its principal place of business and headquarters at 300 Shire Way, Lexington, Massachusetts 02421. Throughout the Class Period, Shire U.S., Inc. marketed and sold Adderall XR in New Jersey and elsewhere. Upon information and belief, Shire U.S., Inc. is the manufacturer and distributor of Adderall XR.

16. Defendant Shire LLC is a Kentucky limited liability company with its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042. Shire LLC is a successor entity to Shire Laboratories, Inc., a party to the anticompetitive reverse payment agreements at issue herein. Shire LLC develops, manufactures, and sells brand and generic pharmaceutical products in the United States, including Adderall XR. Throughout the Class Period, Shire LLC marketed and sold Adderall XR in New Jersey and elsewhere.

17. The true names and capacities, whether individual, corporate, associated or otherwise of certain manufacturers, distributors, managed care organizations ("MCOs") or their alter egos are sued herein as JOHN DOES 1-100 inclusive are presently unknown to Plaintiff who therefore sues these Defendants by fictitious names. Plaintiff will seek leave of this Court to amend the Complaint to show their true names and capacities when the same have been established. Plaintiff is informed and believe and based thereon alleges that JOHN DOES 1- 100 were authorized to do and did business in New Jersey. Plaintiff is further informed and believes and based thereon alleges that JOHN DOES 1-100 were or are, in some manner or way,

responsible for and liable to Plaintiff for the events, happenings, and damages hereinafter set forth below.

18. Plaintiff is informed and believe and based thereon alleges that at all times relevant herein each of the Defendants was the agent, servant, employee, subsidiary, affiliate, partner, assignee, successor-in-interest, alter ego, or other representative of each of the remaining Defendants and was acting in such capacity in doing some or all of the things herein complained of and alleged.

III. JURISDICTION

19. This Complaint is brought pursuant to, among other things, New Jersey's Consumer Fraud Act, *N.J.S.A.* 56:8-1 *et seq.* ("NJCFA"), to seek redress for Defendants' unfair methods of competition, unconscionable acts or practices, and unfair conduct in violation of state law.

20. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d) because the matter in controversy exceeds the sum of $5,000,000, exclusive of interest and costs, and is a class action in which members of the Class of plaintiffs are citizens of a State different from the Defendants.

21. Defendants have sufficient minimum contacts with New Jersey or otherwise have intentionally availed themselves of the consumer markets within New Jersey through the promotion, sale, marketing, and/or distribution of its products in New Jersey and/or to New Jersey residents to render the exercise of jurisdiction by the New Jersey courts permissible under traditional notions of fair play and substantial justice.

22. Defendants transact business within this judicial district, and the interstate trade and commerce described herein is carried out, in substantial part, in this district. Plaintiff resides in this district, purchased Adderall XR and were thereby injured and subjected to irreparable harm in this district. Defendants received substantial compensation and profits from sales of

Adderall XR in this district. Thus, their liability arose in part in this district. Venue is therefore appropriate under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

IV. FACTUAL ALLEGATIONS

A. The Adderall Franchise Transforms Shire Into a Major Pharmaceutical Company

23. Adderall XR is a once-a-day psychostimulant drug of the pherethylamine and amphetamine chemical classes indicated for treatment of attention deficit hyperactivity disorder (ADHD).

24. In 1996, Shire released Adderall in an instant release formulation ("Adderall IR"). Adderall IR quickly became popular as an alternative to methylphenidate (sold under the brand name Ritalin) for treatment of ADHD. Studies indicate that Adderall is slightly more potent and has a longer period of efficacy than Ritalin, especially at lower doses.

25. The active ingredient formulation for Adderall IR has been in the public domain for decades and is thus off-patent. Nevertheless, upon FDA approval of Adderall IR in 1996 for the ADHD indication, Shire was awarded a period of regulatory exclusivity for Adderall IR that expired in 2001. However, Shire recognized and understood that Adderall IR lacked long-term potential without patent protection.

26. In order to protect the Adderall franchise from generic intrusion in 2001, as the Adderall IR period of regulatory exclusivity expired, Shire developed Adderall XR as a "line-extension" product. Adderall XR was released in late 2001, just before generic Adderall IR entry, and Shire had the intention of switching all of its Adderall IR patients to Adderall XR.

27. The switch was largely successful and Adderall XR quickly became a major source of revenue and the flagship product for Shire. Adderall XR transformed Shire from a small company founded in 1986 into a major pharmaceutical company. In the decade following Adderall XR's release, Shire's net sales topped $6 billion. Adderall XR was a major source of Shire's sales, and from its launch through 2008 accounted for almost half of Shire's annual

revenues and in 2008 generated over $1 billion in sales achieving what the pharmaceutical industry refers to as "blockbuster" status.

B. Adderall XR's Patent Protection

28. Upon approval of Adderall XR in late 2001, Shire received a regulatory exclusivity period that lasted until early 2004. However, seeking to extend its Adderall XR monopoly beyond 2004, Shire procured patents of dubious validity concerning the extended release coating for Adderall XR capsules.

29. Shire's Adderall XR patent portfolio consists of U.S. Patent Nos. 6,322,819 ('819 Patent) and 6,605,300 ('300 Patent), which apply not to the active ingredient formulation, but instead cover the release coating allowing for the extended release of the active ingredients.

30. Patents are intended to encourage innovation by offering a monopoly period for inventions that are novel, useful, and non-obvious. However, the reality is that a large number of issued patents should have been rejected. A 2003 report by the Federal Trade Commission ("FTC") found that the average patent application gets approximately 15-20 hours of review time by the U.S. Patent and Trademark Office's ("PTO") assigned examiner. Despite the PTO receiving hundreds of thousands of patent applications each year, approximately eighty-five percent (85%) of patent applications ultimately result in an issued patent.

31. Brand pharmaceutical companies seeking to take advantage of the PTO's limited resources have increasingly applied a patent procurement strategy known as "evergreening." "Evergreened" patents are patents not on the active pharmaceutical ingredient ("API"), but instead are non-API patents on some ancillary aspect of the drug, such as its delivery method or release mechanism. These "evergreened" patents – if litigated to judgment – have a high rate of being found invalid or not infringed.

32. Shire's Adderall XR Patent Portfolio consisted of two evergreened patents on the drug's extended release coating. Numerous Wall Street analysts, generic pharmaceutical companies, and even Shire understood Shire's Adderall XR patent protection to be weak.

C. Generic Challenge to Adderall XR

33. In November 2002, Barr Pharmaceuticals (which was subsequently acquired by Teva Pharmaceuticals USA, Inc. and will subsequently be referred to as "Barr/Teva" unless otherwise denominated separately) filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") to manufacture and sell a generic formulation of Adderall XR it had developed. Barr/Teva's ANDA included what is referred to as a "Paragraph IV certification" which is a declaration by the ANDA filer that it believes the patents covering the registered listed drug ("RLD") are either invalid or not infringed by the ANDA product. Upon service of the Paragraph IV certification, the brand company may elect to initiate Hatch-Waxman patent litigation by filing a patent infringement lawsuit within forty-five (45) days. Such an action triggers a stay preventing the FDA from approving the ANDA until the earlier of thirty (30) months has elapsed or the issuance of a "court decision" finding the patents at issue invalid or not infringed by the ANDA drug ("the 30 month stay").

34. Barr/Teva's ANDA, as the first-filed ANDA, entitled Barr to a lucrative one hundred eighty (180) day exclusivity period ("180 day exclusivity"). The 180 day exclusivity is a statutory incentive set forth in the Hatch-Waxman generic drug approval provisions, 21 U.S.C. § 355(j), for generic pharmaceutical companies to challenge brand manufacturers' patents. The first filer's ANDA – once approved – entitles the first filer to 180 days of generic exclusivity during which the FDA cannot approve other generic companies' later-filed ANDAs. The generic pharmaceutical industry trade group, the Generic Pharmaceutical Association ("GPhA") has asserted that the "vast majority" of generic drug profits occur during the 180 day exclusivity period.

35. As set forth in the Hatch-Waxman Act, the 180 day exclusivity period commences upon a "first commercial launch" by the 180 day exclusivity holder (which applies to both ANDA and authorized generic launches) or upon a "court decision" (interpreted to be a district court decision) finding the patents invalid or not infringed.

36. Although more recent versions of the Hatch-Waxman Act include so-called "forfeiture provisions" in the event that the first-filer delays initiating its 180 day exclusivity, because Barr/Teva's ANDA was filed prior to the Medicare Modernization Act ("MMA") Amendments of 2003, no such forfeiture provisions could apply to the Barr ANDA.

37. Having been served a Paragraph IV letter by Barr/Teva, Shire filed a patent suit alleging infringement of its '819 Patent ("The Barr/Teva '1219 Lawsuit"). Shire filed a subsequent lawsuit against Barr/Teva in September 2003, alleging infringement of its '300 Patent ("The Barr/Teva '6632 Lawsuit"). Both cases were filed in the Southern District of New York. Both cases also triggered 30 month stays, preventing the FDA from approving Barr/Teva's ANDA until July 2005 and February 2006, respectively.

38. In September 2003, Impax Laboratories, Inc. ("Impax") filed the second ANDA seeking to manufacture and sell its generic version of Adderall XR. Once served with Impax's Paragraph IV certification, Shire initiated Hatch-Waxman patent litigation against Impax in December 2003 asserting both the '819 and '300 Patents ("The Impax '1164 Lawsuit"). Shire filed an additional Hatch-Waxman lawsuit against Impax in January 2005 ("The Impax '0020 Lawsuit"), after having received a second Paragraph IV certification for additional dosage strengths. Both cases triggered 30 month stays, preventing the FDA from approving Impax's ANDA until May 2006 and June 2007, respectively. Both cases were litigated in the District of Delaware.

39. In November 2004, Colony Pharmaceuticals, Inc. ("Colony") notified Shire that it had submitted an ANDA. Colony was later acquired by Actavis Elizabeth, LLC ("Actavis"), and

the Colony ANDA and ANDA holder will hereinafter be referred to as "Colony/Actavis." Shire initiated a patent infringement lawsuit against Colony/Actavis in March 2007 pertaining to the '819 and '300 Patents, as well as Shire's 6,916,768 Patent (the '768 Patent, discussed *infra*), filed in the District of Maryland. The Colony/Actavis litigation proceeded mostly under seal (even the court's orders were under seal), and on April 10, 2008 Shire and Colony/Actavis entered into a Settlement and License Agreement settling the patent dispute. Colony/Actavis agreed to sign a consent judgment acknowledging the validity of the Shire patents and that the Colony/Actavis ANDA product infringed Shire's patents. Shire's royalty-bearing license permitted Colony/Actavis to launch its ANDA on the 181st day after Barr's first commercial marketing. This was the earliest date Colony/Actavis could have launched its ANDA.

40. In February 2005, Teva Pharmaceuticals USA, Inc. ("Teva"), notified Shire that it had submitted an ANDA. Shire initiated a patent infringement lawsuit against Teva in March 2006 pertaining to the '819 and '300 patents, filed in the Eastern District of Pennsylvania. Teva filed a counterclaim seeking a declaratory judgment that the '819 and '300 patents, as well as Shire's '768 Patent, were invalid or not infringed by Teva's ANDA product. On March 3, 2008, Shire and Teva entered into a Settlement and License Agreement settling the patent dispute. Teva agreed to sign a consent judgment acknowledging the validity of Shire's patents and that the Teva ANDA product infringed Shire's patents. Shire's royalty-bearing license permitted Teva to launch its ANDA on the 181st day after Barr's first commercial marketing. This was the earliest date Teva could have launched its ANDA. On November 8, 2013, Shire and Teva entered into an Adderall XR Distribution and Supply Agreement wherein Teva was designated as a supplier of Adderall XR authorized generic product.

41. In September 2006, Andrx Pharmaceuticals, LLC ("Andrx") notified Shire that it had submitted an ANDA. In November 2006, Andrx was acquired by Watson Pharmaceuticals, Inc. ("Watson"). In November 2012, Watson acquired Actavis Group. The Andrx ANDA and

ANDA holder will hereinafter be referred to as "Andrx/Actavis." Shire initiated a patent infringement lawsuit against Andrx/Actavis in August 2007 pertaining to the '819 and '300 patents, as well as Shire's '768 Patent, filed in the Southern District of Florida. On November 13, 2007, Shire and Andrx/Actavis entered into a Settlement and License agreement settling the patent dispute. Andrx/Actavis agreed to sign a consent judgment acknowledging the validity of the Shire patents and that Andrx/Actavis's ANDA product infringed Shire's patents. Shire's royalty-bearing license permitted Andrx/Actavis to launch its ANDA on the 181st day after Barr's first commercial marketing. This was the earliest date Andrx/Actavis could have launched its ANDA.

42. In December 2006, Sandoz, Inc. ("Sandoz") notified Shire that it had submitted an ANDA. In January 2007, Shire initiated a patent infringement lawsuit against Sandoz pertaining to the '819 and '300 patents, as well as Shire's '768 Patent, filed in the District of New Jersey. On October 5, 2009, Shire and Sandoz entered into a Settlement and License Agreement settling the patent dispute. Sandoz agreed to sign a consent judgment acknowledging the validity of the Shire patents and that Sandoz's ANDA product infringed Shire's patents. Shire's royalty-bearing license permitted Sandoz to launch its ANDA on October 5, 2009, the very day that the Settlement and License was executed. On December 1, 2013, Shire and Sandoz entered into an Adderall XR Distribution and Supply Agreement wherein Sandoz was designated as a supplier of Adderall XR authorized generic product.

43. Having settled literally every single Adderall XR patent infringement lawsuit with agreed-upon consent judgments "affirming" the validity and enforceability of Shire's patents, Shire evaded negative court decision on its Adderall XR patent portfolio and extended its patent protection.

44. In fact, Shire continues to assert its Adderall XR patents. For example, Neos Therapeutics Inc. ("Neos"), filed an NDA for a competing medication, specifically asserting to

the FDA that Shire's Adderall XR patents are invalid. Shire responded in April 2013 with yet another patent infringement lawsuit. Shortly after the court set a trial date, Shire settled the lawsuit with Neos.

45. Currently pending are at least three (3) patent infringement lawsuits filed by Shire against Corepharma, LLC, Amerigen Pharms., Ltd., and Par Pharmaceutical, Inc., all pending in the District of New Jersey.

D. Shire's Adderall XR Patent Litigation Conduct

46. Shire's litigation conduct further underscored its bad faith use of the '819 and '300 patent litigation to extend its monopoly. For example, the Court in the Shire v. Impax litigation issued its Markman Order affecting claim construction of the '819 and '300 patents in February 2005. The ruling rejected Shire's arguments regarding claim construction, and emboldened Impax in September 2005 to move for summary judgment.

47. In response to the unfavorable Markman Order, and in an effort to prevent the Court from ruling on Impax's Motion for Summary Judgment, Shire in March 2005 requested that the United States Patent Office "re-issue" its '819 and '300 patents pursuant to 35 U.S.C. § 251.

48. Shire unbelievably claimed that discovery in the Barr/Teva litigation, which had been on file for nearly two years, uncovered supposed errors in the '819 and '300 patents. Such was not the case, and Shire, when filing for reissuance, did not even change any of the forty-two (42) claims asserted in those patents, but instead added additional claims. The overburdened PTO eventually granted Shire's reissuance.

49. Shire then argued before the district court that the subsequent patent reissuance was a basis for the court in November 2005 to reconsider the Markman Order. Impax, in response, correctly characterized Shire's actions as "meritless" and "merely yet another desperate attempt to delay consideration of Impax's pending summary judgment motion."

50. The Court ultimately agreed with Impax, denying Shire's Motion for Reconsideration of the unfavorable Markman Order. The Court highlighted Shire's abusive "revolving door" strategy to delay the court from resolving the patent litigation. As stated by the Court:

> Moreover, the court agrees with Impax that allowing Shire to re-open claim construction may lead to a "revolving door," thereby indefinitely preventing the court from reaching a final decision in this litigation. Following Shire's rational to its endpoint, the court can envision a request for supplemental briefing and re-argument after every office action and response thereto until the reissue proceedings conclude. Thus, the Markman process may be never-ending, which would surely frustrate the court's efforts to achieve finality in this consolidated litigation.

Shire Labs., Inc. v. Impax Labs, Inc., No. 03-1164 at *3 (D. Del. Jan. 13, 2006) (citing *Shering Corp. v. Amgen, Inc.*, 25 F. Supp. 2d 293, 299 (D. Del. 1998)).

51. Emboldened by the favorable Markman Order, Impax requested and received leave to file for summary judgment. Impax's summary judgment was fully briefed and under submission on October 18, 2005. In the event that the Impax court issued a judgment against Shire's patents, such judgment would have constituted a "court decision" triggering Barr's 180 day exclusivity. The FDA, in turn, could have approved Barr's ANDA immediately and could have approved other later-filed ANDAs as early as mid-2006. Notably, the FDA had found as early as August 2005 that the Colony/Actavis ANDA had passed the FDA's bioequivalence department's review.

52. Threatened by the possibility that the Impax court, at any point, could issue a judgment against Shire's patents, Shire filed its first citizen petition just days before Impax's summary judgment motion went under submission. Shire later filed two (2) more citizen petitions, disingenuously labeled as "supplements" to Shire's October 2005 citizen petition. All three (3) citizen petition filings were submitted with the purpose of delaying FDA approval of generic ANDA products. In rejecting each and every specific request made by Shire in 2012, the

FDA noted the inconsistency of Shire's citizen petition filings, stating "unclear whether the requests in [Shire's] 2012 Supplement replace[d Shire's] original requests or [were] offered in the alternative."

53. Also, the day after the Impax summary judgment motion going under submission, Shire filed yet another patent suit, this time against both Barr/Teva and Impax and alleging infringement of its '768 patent ("the Barr/Teva & Impax '768 Lawsuit"). This case was filed in the Southern District of New York. The lawsuit was objectively and subjectively baseless and constituted sham litigation.

54. Shire's '768 patent was not even listed in the FDA's Orange Book, so there was unquestionably no basis for a patent suit by Shire. Under the Hatch-Waxman Act, a generic manufacturer has only infringed a patent if it is listed in the Orange Book; otherwise, generic manufacturers have a safe harbor in their preparation activities and there is no infringement until the generic manufacturer actually markets its product. As succinctly stated in Barr/Teva's Motion to Dismiss:

> Shire's infringement claim on the '768 patent must be dismissed for lack of subject matter jurisdiction because Shire did not list the '768 patent in the FDA's Orange Book … and, thus, Barr has not infringed the patent. Indeed, 35 U.S.C. § 271(e) provides that there is no "act of infringement" as a matter of law because Barr's efforts to develop a generic Adderall XR product do not constitute infringement of this unlisted patent.

55. Further, the release-mechanism technology covered by the '768 patent, upon information and belief, was not even employed by Shire in the Adderall XR product. Both in procedure and in substance, the '768 patent suit was a sham filed as an Eleventh Hour attempt to foreclose Impax and/or Barr/Teva from launching generic AXR products in the event either won its '819 and '300 patent litigation.

56. Shire's motivation for using every trick in the book to delay generic entry of Adderall XR is obvious. Absent its assertion of dubious patents, sham litigation, dilatory

litigation tactics, equally dubious citizen petition filings, and eventual reverse payment settlement agreements, Shire faced overwhelming odds that it would have lost the patent litigation with Impax and/or Barr/Teva far sooner than it could delay generic entry through unlawful reverse payment settlement agreements. Of course, the availability of a much cheaper generic would have had profound implications for Shire's bottom line, nearly cutting in half Shire's total revenues as a company.

57. If there was any doubt regarding Shire's subjective motivation for all of its delay tactics, that was settled in November 2005 when Shire's then-CEO, Matt Emmens, gave a remarkably candid interview in which he bragged about Shire's efforts to thwart generic competition for Adderall XR:

> The US is also where the lawyers are, and Mr. Emmens has had to spend a lot of time with them as Shire tries to defend its patents on Adderall, which most analysts forecast will face copycat competition after a courtroom showdown beginning in January. If a copycat version is allowed on the market, Adderall prices will certainly collapse. US parents, insurers and healthcare authorities might very much like that. Mr. Emmens' task is to delay that until Shire's new products have established themselves.
>
> Pharmaceuticals companies expend a great deal of brainpower on tactics for maintaining their monopoly positions, and Shire is trying every tactic in the book. It is pretty pleased with itself to date. It has filed extra patents on the way Adderall is made and is suing the generic drug makers for infringement of that and other patents. And it is asking regulators to insist that the generics firms conduct human trials before being allowed to launch. This last tactic is "pretty elegant," Mr. Emmens says with a smile.
>
> He has experience of this sort of battle, having worked in the joint venture between Merck of the US and Astra of Sweden which developed Prilosec, an ulcer drug which became the world's best-selling medicine. AstraZeneca managed to tie up the manufacturers of generic Prilosec in the courts for nearly two years after the core patents expired, thanks to a plan put in place many years before.

Stephen Foley, Matt Emmens: Shire Pharmaceuticals chief focuses his attention on drugs deficit, The Independent, Nov. 12, 2005.

E. Shire's Unlawful Anticompetitive Reverse Payment Settlement Agreements with Impax and Barr/Teva to Delay Generic Entry

58. In late 2005 and early 2006, the vast majority of Wall Street analysts, the generic manufacturers, and even Shire forecasted that Shire would lose its patent litigation to either Impax and/or Barr/Teva.

59. Shire understood – as set out above – that the two keys to delaying generic entry were to (1) secure an agreement with Barr/Teva (as the first-filer holding the 180 day exclusivity) to delay its "first commercial marketing" of a generic AXR product and (2) prevent any other generic challenger from securing a judgment against Shire's patents that would trigger Barr/Teva's 180 day exclusivity. If Shire could manage both of these things, then Shire and Barr/Teva could bilaterally decide when generic AXR competition would occur.

60. With defeat looming in the Impax litigation, Shire entered into tripartite negotiations with both Impax and Barr/Teva, eventually coming to a three-way deal to delay generic AXR competition until April 2009.

61. Shire settled first with Impax on January 19, 2006. In exchange for dropping its winning patent challenge, Shire made various payments to Impax far exceeding the amount of revenue Impax could have expected to make on its own as a later filer of an AXR ANDA.

62. Upon information and belief, in exchange for settlement, Shire agreed to designate Impax as Shire's Adderall XR authorized generic partner in the event that Barr/Teva did not later settle its own patent litigation with Shire. Such an AG partnership provided Impax with the opportunity to realize generic AXR revenue during the critically important 180 day exclusivity period, which was not otherwise possible for Impax as a later filer. Only by launching an authorized generic through the NDA holder (i.e., Shire) can any company other than the holder of the 180 day exclusivity compete during that time period in which the "vast majority" of generic drug profits are made.

63. Upon information and belief, the authorized generic license to Impax was negotiated at a commercially unreasonably low royalty rate given the circumstances. The low royalty extracted by Shire was in consideration for Impax agreeing to settle the patent litigation and constituted a reverse payment to Impax potentially worth millions of dollars.

64. Moreover, upon information and belief, in the event Barr did settle, Impax was made more than whole by Shire's agreement to allow Impax to launch the first day after Barr's 180 day exclusivity either through its own ANDA or as an authorized generic supplied by Shire.

65. Furthermore, Shire and Impax entered into a "side deal" executed the same day as the Adderall XR patent infringement litigation.

66. "Side deals" are supposedly unrelated business agreements entered into between the parties settling the patent litigation generating the alleged reverse payment settlement agreement to delay generic entry. Although independent business transactions are appropriate, many "side deals" tend to be executed the same day and may constitute a vehicle through which the brand company transfers value to the generic company as part of the reverse payment agreement to delay generic entry. The FTC has attacked such deals, with one official stating that such side deals "prompt the question of whether the [side] deal is designed to persuade the generic to give up an earlier entry date." As noted by Bradley Albert, deputy assistant director of the FTC's health care division, in April 2015, "[i]f a business opportunity is truly independent and makes sense for both parties, then it's gonna make sense a month afterwards."

67. The Shire and Impax "side deal" consisted of a Promotional Services Agreement related to Shire's Carbatrol drug that was executed on January 19, 2006 the very same day as the Adderall XR patent litigation. Upon information and belief, the two deals were linked and the Carbatrol agreement was a sweetener for Impax to settle the Adderall XR litigation.

68. Even Shire's own lawyers recognized that the Carbatrol deal was linked to the Adderall XR settlement. In a publicly available court filing in the *Impax v. Shire* breach of

supply litigation, Shire filed a statement of material facts in opposition to Impax's motion for summary judgment. In that filing, Shire stated: ""The [Adderall XR] litigation also resulted in a promotional agreement between Impax and Shire where Shire agreed to pay Impax to promote Shire's Carbatrol product." *Impax v. Shire*, No. 1:10cv8386 (S.D.N.Y. Feb. 24, 2012) (Dkt. No. 109, at 8).

69. Upon information and belief, the Carbatrol agreement transferred millions of dollars in value and expected value to Impax. Under the terms of the agreement, Shire was to fund and Impax was to manage a contract sales force to promote Shire's Carbatrol product. Along with numerous other payments related to incremental sales and embedded in the agreement itself, numerous analysts noted that Impax would also be able to use the sales force to promote its then-pending approval product Vadova. In a subscription-based report, one analyst stated that the Vadova launch was going to be "funded with other peoples [i.e., Shire's] money."

70. These payments of tens of millions of dollars far exceeded Shire's future anticipated litigation costs. By the date of settlement, the Impax patent litigation had proceeded through fact and expert discovery (the most expensive part of the litigation). Notably, the American Intellectual Property Law Association ("AIPLA") conducted a study in 2007 finding that the total costs for a patent infringement lawsuit with greater than $25 million at risk would average around $7.5 million. Upon information and belief, Shire had already expended a large sum of money by the time the Impax case settled.

71. The payments to Impax far exceeded Shire's future anticipated litigation costs.

72. Further, as with Shire's later patent litigation settlements, the Impax settlement included a consent judgment drafted by the parties that misleadingly sought to create the misimpression to other potential generic manufacturers and to other courts that Shire's patents were valid and that Impax's product actually infringed Shire's patents.

73. Having bought off the most immediately threatening patent challenge, Shire next settled with Barr/Teva on August 14, 2006.

74. Upon information and belief, the Shire settlement with Barr/Teva included an agreement whereby, in exchange for a delayed generic entry date, Shire agreed not to launch a competing authorized generic during Barr's 180 day exclusivity period. Such "no AG" agreements are routinely challenged by the FTC, which views them as anticompetitive market allocation agreements. Such "no AG" agreements can be worth hundreds of millions of dollars to holders of the 180 day exclusivity period. For a drug with as much revenue as Adderall XR, the Barr/Teva "no AG" agreement was no exception.

75. Upon information and belief, Shire also agreed to a royalty structure that provided a commercially unreasonably low royalty rate to Shire. Despite Barr/Teva doing hundreds of millions of dollars of sales of generic AXR during its exclusivity period, Shire's Quarterly 10-Q reports for the Second and Third Quarters of 2009 only state that Shire received $13.6 and $2.2 million in Adderall XR royalties, respectively. Shire did not report receiving any royalties whatsoever thereafter.

76. Further, upon information and belief, Shire made other payments to Barr/Teva in exchange for settlement of the Adderall XR patent litigation and a delayed generic entry date, including, two (2) side deals worth into the hundreds of millions executed the very same day as the Adderall XR patent litigation settlement.

77. In the first side deal, Shire sold the Adderall IR brand to Barr/Teva for $63million, which grossly undervalued the product and which, upon information and belief, was intended to transfer value from Shire to Barr/Teva in exchange for settling the Adderall XR litigation.

78. Shire and Barr/Teva's subsidiary, Duramed, likewise entered into a Women's Health Collaboration agreement whereby Shire agreed to bankroll the U.S. development of

several of Duramed's R&D projects that were in the early stages of research and development ("R&D"). Despite obligating itself to fund up to $165 million in U.S. development costs, the terms of the agreement did not allow Shire to realize any revenue from commercialization of these products in the U.S.

79. The ability of these two side deals to stand on their own drew immediate concern from financial analysts. For example, in an August 15, 2006 investor call hosted by Shire's then-CEO Matt Emmens and Shire's then-CFO Angus Russell, one investor posed the following question:

> Afternoon gents. I'm just wandering [sic] when a side deal is not a side deal, I mean it seems to be to be a transfer of value from Shire to Barr, in effect we pay $165 for products that are mostly Phase II and given the very high operating margin on Adderall [IR] and the two times sale you seem to be paying, they seem to have acquired the asset very cheaply. I think what I'm trying to get at is how comfortable are you that the FDC [sic, FTC] won't start to look at the substance over the form of the transactions?

80. In response, both Emmens and Russell denied that the Adderall IR and Women's Health side deals were linked, asserting that "each transaction stands on its own in terms of NPV [net present value] and product value versus the investment made." Upon information and belief, this statement was inaccurate and/or false and made with the intent to hide the fact that the two side deals were in reality vehicles to transfer hundreds of millions of dollars of value to Barr/Teva in exchange for a delayed generic entry date.

81. The Shire-Impax and Shire-Barr/Teva agreements each carried millions of dollars of reverse payments in exchange for delayed generic entry, and had the effect of preventing *any* generic competition in the market, constituting a conspiracy to restrain trade.

82. Upon information and belief, the multi-year extension of Shire's Adderall XR monopoly imposed a substantial cost on consumers and conferred an enormous benefit to Shire

worth billions of dollars, some of which was shared with Impax and Barr/Teva in exchange for allowing Shire to unlawfully extend its monopoly.

83. As detailed above, with the Barr/Teva delay, other generic manufacturers saw little reason to spend resources litigating with Shire when Shire was willing to offer a license effective date that coincided with the earliest possible date each generic could have entered the market. In this manner, Shire was able to buy off later challengers to avoid any ruling on the validity of Shire's Adderall XR patents.

84. These reverse payments settlement agreements were fraudulently concealed from public and Plaintiff and Class Members could not have learned about them through reasonable diligence. The patent litigations proceeded almost entirely under seal (even court orders were sealed), and the various settlement agreements and side deal agreements are non-public documents that have never been made publicly available. Indeed, the very intent of both Shire and Impax and Barr/Teva, respectively, in structuring the payments was to disguise as best as possible their true nature as payments in exchange for delay. And when anyone questioned the nature of the settlements and side deals, Shire vigorously denied any payments were made, including in the public press releases at the time.

F. Shire's Illegal Managed Care Rebate Strategy

85. Simply delaying generic entry was not enough for Shire. Even after generic AXR products finally entered the market in April and October 2009, Shire endeavored to retain market share through monopolistic and collusive and consumer-unfriendly rebate agreements it negotiated with a number of large MCOs doing business in New Jersey and elsewhere. These unusual rebate agreements induced MCOs to conspire with Shire against patients insured by these very MCOs, and resulted in higher patient co-pays for AXR products.

86. Pharmacy benefit programs are a common component of the health care benefit offered to insured individuals by MCOs.

87. MCOs attempt to control prescription drug expenditures by maintaining a prescription drug formulary designed either by the MCO itself or by a Pharmacy Benefits Manager ("PBM") that is contracted to negotiate rebates with pharmaceutical manufacturers and conduct formulary design. The formulary is a list of medications that have been selected for the purpose of encouraging high quality and cost-effective prescribing of pharmaceuticals within a patient population.

88. The typical formulary design categorizes pharmaceutical drugs by therapeutic class and then assigns the on-formulary drugs within the class to formulary "tiers" based on clinical and cost considerations.

89. Each tier on the formulary has a different patient co-pay level. Generic drugs are found on the lowest co-pay tier (tier 1), while branded drugs have higher patient co-pays (tiers 2 and 3, depending on whether the branded product is preferred or non-preferred). Because patients and insurers are co-payors for prescription drugs, insurers set varying patient co-pay levels (through tier placements) to encourage patients to utilize cheaper drugs where available. In this way, the patient and the MCO share in the cost of a more expensive drug or share in the cost savings of a less expensive drug.

90. Prior to generic entry in April 2009, branded Adderall XR would have placed in either the "preferred" or "non-preferred" tier for branded drugs on virtually all MCOs' formularies, with the preferred/non-preferred distinction depending on a number of factors including the rebates Shire was offering as compared to those offered by other companies with products also indicated to treat ADHD.

91. When a generic equivalent to a branded product is released into the market, MCOs respond by placing the generic into a co-pay tier on their formulary associated with generic drugs, which is substantially lower than that for branded drugs. This is especially true for highly-prescribed medications such as Adderall XR that will see substantial generic utilization.

MCOs place such generic drugs on the lower co-pay tier to encourage utilization of cheaper generic equivalents.

92. Having placed the generic product in the lowest co-pay tier to incentivize utilization by patients, and in order to further encourage generic utilization, MCOs will then place the branded product in a non-preferred branded position (e.g., tier 3 on the typical three-tier formulary) with an even higher co-pay than for preferred branded drugs.

93. Formulary management is one of the primary drivers of generic substitution, with substitution rates quickly reaching ninety percent (90%) or higher within one (1) year of generic entry before leveling out.

94. Upon the Barr/Teva and Impax generic launches in April and October 2009, respectively, all or substantially all MCOs would have placed both companies' generic AXR on tier 1 of their formularies, with the lowest patient co-pay, regardless of whether the drug was coded as "generic" or "multi-source brand." This is because, in the absence of Shire rebates, the generic AXR products were significantly cheaper than the listed price for branded AXR. Publicly available data confirms that the vast majority of insurers placed generic AXR on tier 1.

95. However, in the months leading up to Barr/Teva's generic AXR launch and after, Shire targeted several of the largest MCOs in New Jersey and elsewhere with a novel rebate strategy entirely without precedent. Ultimately, this rebate strategy proved disruptive to the very structure of managed care and health insurance pharmacy benefits and contravened legislation and policy, including the Hatch-Waxman Act as well as state mandatory generic substitution laws, designed to expedite generic entry, encourage generic utilization as a cost-saving measure for all payors, and mandate the passing of savings on to the consumer. In short, this exclusionary rebate strategy caused ascertainable losses to consumers and violated public policy in New Jersey and elsewhere.

96. In exchange for substantial rebates described in Shire's SEC filings (*see, e.g.*, Shire's Form 10-Q's filed in the Second and Third Quarters of 2009 ("The Managed Care rebate percentage increased due to higher rebates offered to MCOs from April 1, 2009.")), the MCOs, upon information and belief, were required to disadvantage the generic AXR products on their formularies as compared to Adderall XR. Shire termed this its "managed care/Medicaid strategy" in litigation documents filed in the *Impax v. Shire* breach of supply litigation.

97. Upon information and belief, this was accomplished through formulary tier placements, as well as a number of other contrivances, such as NDC blocks or making non-reimbursable the generic AXR products altogether, as per Shire's rebate agreements. Upon information and belief, these monopolistic disadvantaging/blocking provisions were demands placed by Shire on the MCO in order to drive utilization toward the branded product, resulted in supra-competitive prices, and constituted unlawful exclusionary conduct.

98. In addition, upon information and belief, Shire bundled these Adderall XR rebates with rebates for its other branded products, including Vyvanse, thus conditioning the receipt and/or amount of rebates for Vyvanse upon entering into rebate agreements for branded AXR.

99. Both Shire and the MCOs received substantial benefit from these rebate agreements, at the expense of patients. Shire viewed the strategy as so successful that it defended the Impax v. Shire supply litigation primarily on the effectiveness of the rebate strategy. As stated by Impax, "Shire has put the effectiveness of its purported managed care strategy at issue in this case." Shire prevented the normal generic erosion process from taking place, in essence lowering the cost to MCOs for branded Adderall XR in order to utilize the MCOs' formulary placements and other controls to maintain volume of sales. In exchange, the unusually high rebates meant that MCOs paid less for Adderall XR than for generic AXR. In this way, both Shire and the insuring MCO received the benefit of the bargain.

100. However, insured patients of participating MCOs were harmed due the unavailability of generic AXR and typical generic co-pays. Shire's long-term goal was to transition Adderall XR patients to Vyvanse, but Shire was prohibited from marketing Vyvanse as clinically superior or making any kind of superiority argument with respect to Vyvanse. Thus, Shire understood that well-controlled patients on Adderall XR would be unwilling to switch to Vyvanse once generic AXR was available at cheaper generic co-pays. At the same time, Shire also recognized that – as co-payors for prescription drugs – the higher the patient's co-pay for Adderall XR, the lower the MCO's corresponding co-pay. Consequently, Shire encouraged and/or required participating MCOs to maintain Adderall XR on tier 2 of their formularies while at the same time implementing the severe restrictions on the generic AXR products, such as NDC blocking or non-reimbursement altogether.

101. Thus, while non-participating insurers uniformly made generic AXR available at tier 1 co-pays, participating insurers were required and/or encouraged to maintain Adderall XR at tier 2 co-pays. While Shire and the participating MCOs both gained through these collusive rebate agreements, it was the consumers of Adderall XR and generic AXR and the insured patients of these MCOs who were victimized. Shire's rebate strategy effectively severed the alignment of interest between the insuring MCOs and patients as co-payors for prescription drugs. Instead, the new alignment was between the pharmaceutical company and the insurer.

102. Upon information and belief, some of New Jersey's largest MCOs, including one of its largest insurers, United Health Care, entered into precisely these kinds of rebate agreements with Shire.

103. In addition, the vast majority of rebate agreements were signed in the March 2009 timeframe, just before Teva's generic launch. Upon information and belief, many of the participating MCOs were aware of the others' negotiations with Shire (either by direct contact

with each other or through group meetings such as advisory boards arranged by Shire) and such knowledge became a component of these MCOs' ultimate decision to rebate with Shire.

104. According to statements by Shire in publicly available litigation filings in the Impax v. Shire breach of supply litigation, Shire's rebate strategy allowed Shire to "maintain[] between 35% and 48% of the total Adderall XR market." This represents nearly a forty percent (40%) increase in the market share Shire would have kept in the absence of these agreements.

105. These unconscionable, misleading, and unfair rebate agreements were concealed from consumers, were inherently anticompetitive, were misleading and deceptive, caused Plaintiff an ascertainable loss and directly resulted in supracompetitive consumer co-pays and co-insurance for Adderall XR and generic AXR, violating the New Jersey Consumer Fraud Act, the New Jersey Antitrust Act, and Sections 1 and 2 of the Sherman Act.

G. Effect on Interstate Commerce, Market Power and Competition

106. At all relevant times, Defendants manufactured, sold, and shipped Adderall XR across state lines including into New Jersey.

107. At all relevant times, in connection with its sales of Adderall XR, monies, contracts, bills, and business communications were transmitted continuously and uninterruptedly across state lines, including into New Jersey.

108. At all relevant times, various devices were employed to commit the illegal acts described herein, including U.S. mail, interstate travel, interstate telephone communications, and interstate commerce. Defendants' complained-of activities occurred within the stream of, and have substantially affected, interstate commerce.

109. In this case, as alleged herein, there is direct proof of Defendants' monopoly power over the price of Adderall XR. This direct proof includes, but is not limited to: (a) Shire's exclusion of competition from the market by way of its agreements with Teva and Impax; (b) Shire's monopolistic, collusive, and conspiratorial rebate strategy that caused patients to pay

supracompetitive prices for Adderall XR; (d) Shire's unprecedented market share for Adderall XR after generic drugs are introduced into the marketplace; (e) Shire's status as the only supplier of Adderall XR; (f) price data demonstrating Shire's ability to raise its prices without losing sufficient sales to render the price increases unprofitable; and/or (g) the lack of non-Adderall XR drug products that can be reasonably substituted for Adderall XR.

110. The relevant product market is Adderall XR and its generic equivalents in all dosage forms and strengths.

111. The relevant geographic market is nationwide. Through the illegal conduct described herein, Defendants were able to charge artificially high prices without losing substantial sales, and thus, by definition, maintained monopoly power over Adderall XR products sold in the United States and New Jersey.

112. Through the illegal conduct described herein, Defendants intentionally, purposefully, and successfully suppressed competition. Defendants' exclusionary conduct suppressed the sale of Adderall XR in the United States and New Jersey, and unlawfully enabled Defendants to sell Adderall XR Product at artificially inflated prices.

113. During the relevant time period, Plaintiff and Class Members purchased Adderall XR indirectly from Defendants. As a result of Defendants' anticompetitive and illegal conduct, Plaintiff and Class Members were forced to pay more money in the form of higher patient co-pays for "brand name" medication even though it was precisely the same as the generic AXR products. This is because Plaintiff and Class Members were deprived of the ability to purchase lower-priced generic AXR at competitive market prices.

114. Thus Plaintiff and the Class Members, as a result of Defendants' illegal conduct, have suffered monetary losses and damages.

H. Factual Allegations as to Named Plaintiff

115. Plaintiff is a resident of Passaic County, New Jersey, and was prescribed Adderall XR during the Class Period.

116. Plaintiff has had an insurance policy through United Healthcare, Cigna Healthcare, Oxford Healthcare, Aetna Healthcare, and Blue Cross / Blue Shield. Upon information and belief, the co-pay amounts paid changed based on where a particular drug was placed on the insurer's formulary.

117. Upon information and belief, Plaintiff was required to pay a higher co-pay for Adderall XR than patients typically pay for drugs where a generic option is available, and – upon information and belief – the co-pay was more than Plaintiff would have paid had Defendants not entered into an unlawful rebate agreement with the Plaintiff's insurer.

118. Plaintiff was an indirect purchaser of Adderall XR.

I. Fraudulent Concealment and Tolling

119. Upon information and belief, Shire has affirmatively concealed from Plaintiff and other Class members its unlawful conduct. Shire planned and implemented its unlawful schemes in private, and affirmatively strove to avoid discussing or disclosing that schemes, and took other actions to hide and conceal the unlawful conduct.

120. For instance, the patent infringement litigations proceeded mostly under seal, and the nature of these settlement agreements and related side deals and reverse payment arrangements in order to delay generic entry were fraudulently concealed from the public and from Plaintiff. Shire orchestrated a "three-way deal" with Impax and Barr/Teva that included numerous non-public and disguised payments to delay generic entry that Plaintiff and class members could not have discovered with reasonable diligence. For example, Shire negotiated a sweetheart authorized generic partnership with Impax to plus a promotional services side deal worth millions of dollars (*see, e.g.*, ¶¶ 60-65, 67, 73-74).

121. Shire then negotiated with Barr an agreement not to launch an authorized generic and also required an unreasonably low royalty rate with Barr, all to delay Barr's generic entry (*see, e.g.*, ¶¶ 75) to April 2009. In addition, Shire sold the rights to Adderall IR at a fifty (50%) discount (*see, e.g.*, ¶ 77), and made millions of dollars in payments to Barr through yet another side deal for a women's health collaboration (*see, e.g.*, ¶ 78).

122. The precise terms of these agreements were not revealed to Plaintiff or other class members. Contrary to the non-public terms of the settlements and side deals Shire entered into with generic manufacturers, Shire publicly represented, for instance in its SEC filings, that "[n]o payments to Barr [or Impax] are involved in the settlement agreement[s]." Shire never disclosed the anticompetitive negotiations and terms set forth above, as it was Shire's intention to deceive Plaintiff and other Class members.

123. Additionally, Shire negotiated collusive rebate agreements in secret, the terms of which were not publicly disclosed or otherwise made known or available to Plaintiff and other Class members. This was done with the intention of deceiving Plaintiff and other Class members.

124. Because of the above, Plaintiff and other class members did not discover, nor could they discover through reasonable diligence, Shire's deceptive, fraudulent, anticompetitive, and unlawful conduct alleged herein. Shire's false and misleading explanations, or obfuscations, lulled Plaintiff and Class members into believing that the prices paid for Adderall XR were the result of competitive market force rather than collusive or monopolistic, anticompetitive practices.

125. As a result of Shire's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class members has been tolled. Plaintiff and other Class members exercised reasonable diligence by among other things promptly investigating the allegations contained herein after sufficient information was

discoverable. Despite other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

126. Shire's unlawful conduct alleged herein and the effects thereof are continuing and, as a direct and proximate result, Plaintiff and Class members have and continue to suffer ascertainable losses.

V. CLASS REPRESENTATION ALLEGATIONS

A. Class Definition

127. Plaintiff brings this action pursuant to Federal Rules of Civil Procedure 23(b)(2) and (b)(3) on behalf of themselves and on behalf of the Class defined below. The proposed Classes are:

> **1. <u>The "Reverse Payment" Class:</u> All persons who paid (for personal or household use) some or all of the purchase price for brand Adderall XR in the United States between January 1, 2007 through March 31, 2009.**

> **2. <u>The "Rebate" Class:</u> All persons who paid (for personal or household use) some or all of the purchase price for brand Adderall XR in the United States between April 1, 2009 through the present.**

128. Excluded from the Class are: (1) Third Party Payors; (2) Persons and entities who purchased directly from Defendants; (3) Persons and entities who purchased only for resale purposes; (4) "Flat co-pay" "Cadillac Plan" customers who made purchases only via fixed dollar co-payments that do not vary between a branded pharmaceutical and a generic equivalent; (5)

Patients with insurance coverage including a flat-rate co-pay provision; (6) Governmental entities; (7) Shire, their officers, directors, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries and assigns, and entities in which Shire has a controlling interest; and (8) The judge, justices, magistrates or judicial officers presiding over this matter.

129. Said definition may be further defined or amended by additional pleadings, evidentiary hearings, a class certification hearing, and orders of this Court.

B. Fed. R. Civ. P. 23(a) Factors

130. **Numerosity.** The members of the Class are so numerous that separate joinder of each member is impracticable. Plaintiff does not know the exact number of members in the Class, but based upon information and belief, Plaintiff reasonably believes that Class Members number at a minimum in the thousands.

131. **Commonality.** The claims of Plaintiff raise questions of law or fact common to the questions of law or fact raised by the claims of each member of the Class. Plaintiff's claims arise from the same practice or course of conduct that gives rise to the claims of the Class members. The questions of law and fact common to Plaintiff and the Class predominate over questions affecting only individual Class members, and include, but are not limited to, the following:

- Whether Defendants' rebate agreements constitute the illegal restraint of trade in violation of Section 1 of the Sherman Act and/or New Jersey Antitrust Act.
- Whether Defendants' violations of Section 1 of the Sherman Act constitute violations of the NJCFA;
- Whether Shire's patent infringement lawsuits filed against Teva, Impax and others were filed with the improper purpose of preventing entry of competing generic products into the market, in violation of Section 2 of the Sherman Act and/or New Jersey's Antitrust Act;
- Whether Defendants' intentional breach of the supply agreements constitute monopolization and/or attempted monopolization in violation of Section 2 of the Sherman Act and/or New Jersey's Antitrust Act;

- Whether Defendants' rebate agreements constitute monopolization and/or attempted monopolization and/or conspiracy to monopolize in violation of Section 2 of the Sherman Act and/or New Jersey's Antitrust Act;
- Whether Defendants' rebate agreements constitute unlawful exclusive dealing under the FTC Act, the Sherman Act, and/or the NJCFA;
- Whether Defendants' rebate agreements constitute an unlawful tying violation under the FTC Act, the Sherman Act, and/or the NJCFA;
- Whether Defendants' rebate agreements constitute unlawful predatory pricing under the FTC Act, the Sherman Act, and/or the NJCFA;
- Whether consumers paid supracompetitve prices for Adderall XR products on account of Defendants' unlawful rebate agreements;
- Whether Defendants' violations of Section 2 of the Sherman Act constitute violations of the NJCFA;
- Whether Defendants' conduct violated the New Jersey Antitrust Act;
- Whether Defendants' violations of the New Jersey Antitrust Act constitute violations of the NJCFA;
- Whether a relevant market needs to be defined in this case in light of the existence of direct evidence of Defendants' power to exclude generic competition and set supracompetitive prices for Adderall XR Product;
- If a relevant market needs to be defined, the definition of the relevant market for analyzing Defendants' monopoly power, and whether Defendants had monopoly power in the relevant market;
- Whether, independent of whether Defendants' conduct violated the Sherman Act or New Jersey's Antitrust Act, Defendants' conduct constitutes unfair and/or fraudulent practices in violation of the NJCFA; and/or
- Whether Plaintiff and the Class have been injured as a result of Defendants' anti-competitive conduct, and the amount of damages.

132. **Typicality.** The claims of Plaintiff are typical of the claims of each member of the Class. Defendants engaged in a standardized course of conduct affecting the Class Members, and Plaintiff's alleged injuries arise out of that conduct. All Class Members, including Plaintiff, have the same or similar injury to their property (i.e. paying higher prices for Adderall XR) as a result of Defendants' anti-competitive conduct.

133. **Adequacy.** Plaintiff can fairly and adequately protect and represent the interests of each member of the Class. Plaintiff fits within the class definition and her interests do not conflict with the interest of the members of the Class she seeks to represent. Plaintiff is represented by experienced and able attorneys. The undersigned Class Counsel have litigated numerous class actions and complex cases and intend to prosecute this action vigorously for the benefit of the entire Class. Plaintiff and Class Counsel can and will fairly and adequately protect the interests of all members of the Class.

B. Fed. R. Civ. P. 23(b)(2) Factors

134. Defendants acted on grounds generally applicable to the entire Class, thereby making final injunctive relief and/or corresponding declaratory relief appropriate with respect to the Class as a whole. The prosecution of separate actions by individual Class Members would create the risk of inconsistent or varying adjudications with respect to individual members of the Class that would establish incompatible standards of conduct for Defendants.

135. Injunctive relief is necessary to prevent further anti-competitive conduct by Defendants. Money damages alone will not afford adequate and complete relief, and injunctive relief is necessary to restrain Defendants from continuing to engage in conduct which restrains, suppresses, and/or eliminates competition in the United States and New Jersey for the sale of Adderall XR.

D. Fed. R. Civ. P. 23(b)(3) Factors

136. **Common issues predominate:** As set forth in detail above, common issues of fact and law predominate because all of Plaintiff's claims are based on identical anti-competitive conduct.

137. **Superiority:** Additionally, a class action is superior to other available methods for fair and efficient adjudication of the controversy. The damages sought by each Class Member are such that individual prosecution would prove burdensome and expensive given the

complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for the members of the Class to effectively redress the wrongs done to them on an individual basis. Even if the members of the Class themselves could afford such individual litigation, it would be an unnecessary burden on the courts.

138. The trial and litigation of Plaintiff's claims are manageable. Individualized litigation presents a potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and to the court system presented by the legal and factual issues raised by Defendants' conduct. By contrast, the class action device will result in substantial benefits to the litigants and the Court by allowing the Court to resolve numerous individual claims based upon a single set of proof in just one case.

139. Further, Defendants have acted on grounds generally applicable to the Class, thereby making final injunctive relief with respect to the Class as a whole appropriate. Moreover, on information and belief, Plaintiff alleges that the conduct complained of herein is substantially likely to continue in the future if an injunction is not entered.

140. **Notice to the Class:** Notice to the Class may be made by publication.

VI. CAUSES OF ACTION

A. First Cause of Action: Violations of the Consumer Fraud Act, *N.J.S.A.* 56:8-1, *et seq.* (premised on Section 1 of the Sherman Act)

141. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

142. Plaintiff and the Class are "persons" within the meaning of *N.J.S.A.* 56:8-1(d).

143. Defendants' conduct alleged herein relating to the sale of Adderall XR constitutes a "sale" within the meaning of *N.J.S.A.* 56:8-1(e).

144. NJCFA declares unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise,

misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby[.]" *N.J.S.A.* 56:8-2.

145. Violations of Section 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) constitute unfair, unconscionable, and/or deceptive acts or practices in violation of NJCFA and New Jersey Antitrust Act.

146. By violating Section 1 of the Sherman Act, 15 U.S.C. § 1, Defendants have violated the Federal Trade Commission Act and engaged in unfair competition and/or unconscionable/unfair acts or practices in violation of NJCFA and New Jersey Antitrust Act.

147. Further, by violating Section 1 of the Sherman Act, Defendants violated a statute proscribing an unfair method of competition.

148. Further, by violating Section 1 of the Sherman Act, Defendants have engaged in an unfair practice. Defendants' violations of Section 1 of the Sherman Act offend established public policy, and are unconscionable and caused consumers to suffer ascertainable losses.

149. Defendants violated Section 1 of the Sherman Act by engaging in the unlawful, anti-competitive conduct set forth herein. Defendants have unreasonably restrained trade and commerce in the relevant product market in violation of Section 1 of the Sherman Act. But for the anti-competitive practices Defendants would not have been able to maintain their monopoly power over the price of Adderall XR in the relevant market.

150. Defendant acted in concert with Barr/Teva, Impax, and other generic manufacturers in furtherance of the illegal restraint of trade complained of herein.

151. Shire's agreements with Barr/Teva and Impax were comprised of large and unjustifiable payments from Shire to Barr/Teva and Impax, who in turn agreed to delay entry

into the market. As such, this is an unreasonable restraint of trade. The agreements and various side deals were for no purpose other than delay the generic manufacturers' entry into the drug market and offered no pro-competitive benefits.

152. Defendants acted in concert with managed care organizations that participated in Shire's illegal rebating strategy in furtherance of the illegal restraint of trade complained of herein. The provisions of these agreements and attendant use of them by Shire constituted unlawful exclusive dealing, unlawful tying, as well as unlawful incentives on consistent supply.

153. Defendants' rebate agreements constitute *per se* unreasonable restraints of trade. Alternatively, the rebate agreements had an unreasonable adverse effect on competition in the properly defined relevant market, and are subject to "quick look" scrutiny.

154. Competition, including price competition at the consumer level for Adderall XR (through the emergence of generic alternatives) will continue to be restrained, suppressed or eliminated as a result of Defendants' anti-competitive conduct described herein. The actual adverse effects of these agreements include, but are not limited to:

- Shire's control of the Adderall XR and Authorized Generic market;
- The delayed entry of generic competition into the Adderall XR market;
- Higher prices for brand name Adderall XR(due to market unavailability of generic AXR and illegal rebating strategy).

155. The agreements were further *per se* anticompetitive for these reasons.

156. Here, the relevant market is Adderall XR and generic equivalents sold nationwide.

157. Competitors, actual and potential, have been, and will continue to be, restrained from vigorously competing with one another for selling Adderall XR as a result of Defendants' anti- competitive conduct.

158. Indirect purchasers (including Plaintiff and members of the putative Class), have been injured in their business and property because they have been deprived of choice, and have paid inflated prices for Adderall XR (or paid higher co-pays for brand name medications), which they otherwise would not have had to pay in the absence of Defendants' anti-competitive conduct. Plaintiff's and the Class's injuries flow from Defendants' unlawful conduct.

159. Because of Defendants' violations of Section 1 of the Sherman Act (and hence NJCFA and New Jersey Antitrust Act), consumers (including Plaintiff and the Class) were deprived of a less expensive generic product, and were forced to purchase a more expensive brand name product. These are the types of injuries the Sherman Act seeks to prevent.

160. As a direct and proximate result of Defendants' violations of Section 1 of the Sherman Act (and hence NJCFA and New Jersey Antitrust Act), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

161. There is no federal or state law which affirmatively authorizes Defendants to engage in the unfair conduct alleged throughout this Complaint.

162. In addition to actual damages, Plaintiff and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to *N.J.S.A.* 56:9-12.

B. Second Cause of Action: Violations of the Consumer Fraud Act, *N.J.S.A.* 56:8-1, *et seq.* (premised on Section 2 of the Sherman Act)

163. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

164. By violating Section 2 of the Sherman Act, 15 U.S.C. § 2, Defendants have violated the Federal Trade Commission Act and engaged in unfair competition and/or an unconscionable/unfair act or practice in violation of New Jersey Antitrust Act and NJCFA.

165. Further, by violating Section 2 of the Sherman Act, Defendants violated a statute proscribing an unfair method of competition.

166. Further, by violating Section 2 of the Sherman Act, Defendants have engaged in an unfair practice. Defendants' violations of Section 2 of the Sherman Act offend established public policy, are unconscionable, are contrary to the NJCFA and caused Plaintiff and the Class to suffer ascertainable losses.

167. Defendants violated Section 2 of the Sherman Act. Defendants attempted to and successfully monopolized power over the price of Adderall XR, and over the relevant market—Adderall XR and its generic equivalents—nationwide and in the State of New Jersey. But for Defendants' exclusionary practices, as set forth above, Defendant would not have been able to maintain its monopoly power over the price of Adderall XR in the relevant market.

168. Defendant violated Section 2 of the Sherman Act in two ways, and taken together further illustrate a successful attempt to exert an illegal monopoly of the price of AXR and over the relevant market. Defendants (1) entered into illegal reverse payment settlement agreements to delay generic entry; and (2) entered into illegal managed care rebate agreements to retain Adderall XR after generic equivalents came to market. All of these actions were done to restrict generic AXR output and furthered Defendants' monopolization of the AXR market, excluding generic manufacturers from participating.

169. During the relevant period, Defendants willfully and unlawfully maintained their monopoly power by excluding and impeding competition from the market for Adderall XR. The goal, purpose and/or effect of the scheme was to prevent, delay, and/or minimize the success of the entry of generic AXR competitors, who would have sold generic versions nationwide and in New Jersey at prices significantly below Defendants' prices for Adderall XR, and therefore would have taken most of Defendants' market share. Such generic competition would have effectively caused the average market price of Adderall XR to decline dramatically.

170. Defendants have willfully acquired and/or maintained their monopoly power over the market for the sale of Adderall XR, not through superior skill and/or product, business acumen, or enterprise, but rather through the foregoing anti-competitive and exclusionary conduct. Defendants' conduct in engaging in the sham patent litigation, illegal settlement and rebate agreements ran afoul of Section 2 of the Sherman Act.

171. There is no appropriate or legitimate business justification for the actions and conduct that have facilitated Defendants' monopolization of the United States market for the sale of Adderall XR.

172. Direct purchasers, and indirectly their consumers (including Plaintiff and members of the putative Class), have been injured in their business and property because they have been deprived of choice, and have paid inflated prices for Adderall XR or generic AXR, which they otherwise would not have had to pay in the absence of Defendants' anti-competitive conduct. Plaintiff's and the Class's injuries flow from Defendants' unlawful conduct.

173. Because of Defendants' violations of Section 2 of the Sherman Act (and hence New Jersey Antitrust Act and NJCFA), consumers (including Plaintiff and the Class) were deprived of a less expensive generic product, and were forced to purchase a more expensive brand name product. These are the types of injuries the Sherman Act seeks to prevent.

174. As a direct and proximate result of Defendants' violations of Section 2 of the Sherman Act (and hence NJCFA), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

175. In addition to actual damages, Plaintiff and the Class are entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to *N.J.S.A.* 56:9-12.

C. Third Cause of Action: Violations of the Consumer Fraud Act, *N.J.S.A*, 56:8-1 *et seq.* (premised on New Jersey Antitrust Act)

176. Plaintiff repeats and re-alleges the allegations set forth above, and incorporate the same as if set forth herein at length.

177. By violating the New Jersey Antitrust Act, *N.J.S.A.* 56:9-1 *et seq.* ("NJAA"), Defendants have engaged in unfair competition and/or an unconscionable/unfair act or practice in violation of NJCFA.

178. Further, by violating the NJAA, Defendants violated a statute proscribing an unfair method of competition.

179. Further, by violating the NJAA, Defendants have engaged in an unfair practice. Defendants' violations of the NJAA offend established public policy, are unconscionable, and caused Plaintiff and the Class ascertainable losses.

180. Defendants violated the NJAA. The NJAA was adopted to foster effective competition and complement the body of federal law (including the Sherman Act) prohibiting restraints of trade or commerce. Under the NJAA, every contract, combination, or conspiracy in restraining New Jersey trade or commerce is unlawful. It is further unlawful to monopolize or attempt to monopolize any part of New Jersey trade or commerce.

181. Defendants are "persons" within the meaning of *N.J.S.A.* 56:9-2(a).

182. Adderall XR is a "commodity" within the meaning of *N.J.S.A.* 56:9-2(c), and therefore Defendants' business marketing, selling, and/or distributing Adderall XR is "trade or commerce" within the meaning of *N.J.S.A.* 56:9-2(b).

183. The actions described herein, including but not limited to (1) the illegal and anticompetitive reverse payment settlement agreements to delay generic AXR entry, and (2) the illegal managed care rebate agreements constitute illegal restraints of trade, monopolization of

trade and/or an attempt or conspiracy to monopolize trade or commerce in New Jersey and the United States.

184. As a result of the actions described herein, Defendants attempted to acquire a monopoly in New Jersey and the United States, possessed a monopoly power in New Jersey and the United States which affected the price of Adderall XR, and acquired that monopoly power in an exclusionary manner.

185. Through the actions described herein, Defendants—throughout the United States including New Jersey—possessed the ability to affect price and/or output. The illegal rebate agreements were intended to and did affect the price of Adderall XR in the market.

186. Defendants' wrongful conduct had a substantial anticompetitive effect on commerce within the State of New Jersey and nationwide.

187. The anticompetitive effect of Defendants' actions aside, Defendants' conduct in misallocating the supply of Adderall XR and price-fixing are *per se* violations of the NJAA.

188. As a direct and proximate result of Defendants' violations of the NJAA (and hence NJCFA), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

189. In addition to actual damages, Plaintiff and the Class are entitled to treble damages, declaratory and injunctive relief, as well as reasonable attorney's fees and costs pursuant to *N.J.S.A.* 56:9-12(a).

D. Fourth Cause of Action: Violations of the Consumer Fraud Act, *N.J.S.A.* 56:8-1, *et seq.* (unfair practices – not premised on violations of Sherman Act or New Jersey Antitrust Act)

190. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

191. Independent of whether Defendants' conduct violated the Sherman Act or NJAA, Defendants' conduct, as described throughout the complaint, constitutes unfair practices in violation of NJCFA.

192. First, by utilizing sham patent litigation to delay the entry into the market of generic version of AXR, Defendants engaged in an unfair practice which caused Plaintiff and the Class to pay more for Adderall XR than they would have but for this wrongful conduct.

193. Second, by entering into monopolistic, collusive, and conspiratorial managed care rebate agreements, Defendants endeavored to retain market share and participating MCOs hoped to pay less for reimbursing Adderall XR through steep rebates and the ability to continue to require patients to pay a branded Adderall XR co-pay even after generic AXR market entry.

194. Defendants' unfair practices, as described herein, offend established public policy, are unconscionable, and caused ascertainable losses to consumers. Defendants forced users of its prescription medication, who had no reasonable alternatives, to pay higher prices well into the period in which generic alternatives to Adderall XR should have been available. Defendants were motivated solely by profit at the expense of Plaintiff and the Class.

195. As a direct and proximate result of Defendants' unfair practices (which violate NJCFA), Plaintiff and the Class have suffered a loss of money and suffered actual damages.

196. In addition to actual damages, Plaintiff and the Class are entitled to treble damages, declaratory and injunctive relief, as well as reasonable attorney's fees and costs pursuant to *N.J.S.A.* 56:8-19.

E. Fifth Cause of Action: Violations of the Consumer Fraud Act, *N.J.S.A.* 56:8-1, *et seq.* (deceptive acts – not premised on violations of Sherman Act or New Jersey Antitrust Act)

197. Plaintiff repeats and realleges the allegations set forth above, and incorporate the same as if set forth herein at length.

198. Independent of whether Defendants' conduct violated the Sherman Act or NJAA, Defendants' conduct, as described throughout the complaint, are unconscionable acts which resulted in ascertainable loss in violation of NJCFA.

199. Plaintiff brings this count on her own behalf and on behalf of all Class members.

200. Defendants' sale of pharmaceuticals constitutes trade or commerce under NJCFA.

201. Plaintiff and Class members are persons under *N.J.S.A.* 56:8-1(d) who purchased Adderall XR for personal use, and not for resale.

202. Each Defendant is a "person" or "entity" as used in the NJCFA.

203. Defendants engaged in deceptive conduct in violation of the New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-1, *et seq.* when they, among other things, (1) entered into illegal and anticompetitive reverse payment settlement agreements to delay generic AXR entry and (2) entered into illegal managed care rebate agreements with MCOs to retain market share and maintain elevated prices for Adderall XR and generic AXR. Defendants' conduct constitutes unconscionable, deceptive, fraudulent acts and caused ascertainable losses for Plaintiff and the Class.

204. The goal, purpose and/or effect of Defendants' deceptive scheme was to prevent, delay, and/or minimize access to generic AXR products, which would have been available nationwide and in New Jersey at prices significantly below Defendants' prices for Adderall XR.

205. As a direct and proximate result of Defendants' unconscionable conduct, Plaintiff and Class members were deprived of the opportunity to purchase a generic version of Adderall XR as alleged herein.

206. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive and unconscionable acts alleged herein. The injury consists of paying higher prices for Adderall XR and generic AXR prescription drugs than

they would have paid in the absence of these violations. This injury is of the type *N.J.S.A.* 56:8-1, *et seq.* was designed to prevent and directly results from Defendants' unlawful conduct.

207. In addition to actual damages, Plaintiff and the Class are entitled to treble damages, declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to *N.J.S.A.* 56:8-19.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and on behalf of the members of the Class defined herein, request judgment and relief on all Causes of Action as follows:

A. An order certifying that the action may be maintained as a Class Action;

B. The acts alleged herein be adjudged and decreed to be unfair, deceptive, unconscionable and/or fraudulent business practices violating NJCFA and NJAA;

C. That judgment be entered against Defendants, and each of them jointly and severally, for damages as a result of Defendants' NJCFA and NJAA violations;

D. That judgment be entered against Defendants and in favor of Plaintiff and the Class on the Plaintiff's NJCFA and NJAA claim, for treble damages, actual and consequential damages, equitable relief, including restitution and restitutionary disgorgement;

E. An order enjoining Defendants from pursuing the policies, acts, and practices complained of herein;

F. Actual damages;

G. For pre and post-judgment interest from the date of filing this suit;

H. Reasonable attorneys' fees with an appropriate enhancement under *Rendine v. Pantzer,* 141 *N.J.* 292 (1995);

I. Costs of this suit; and

J. Such other and further relief as the Court may deem necessary or appropriate.

JURY TRIAL DEMANDED

Dated: **September 30, 2015**

Respectfully submitted,

/s/ Gerald Clark

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